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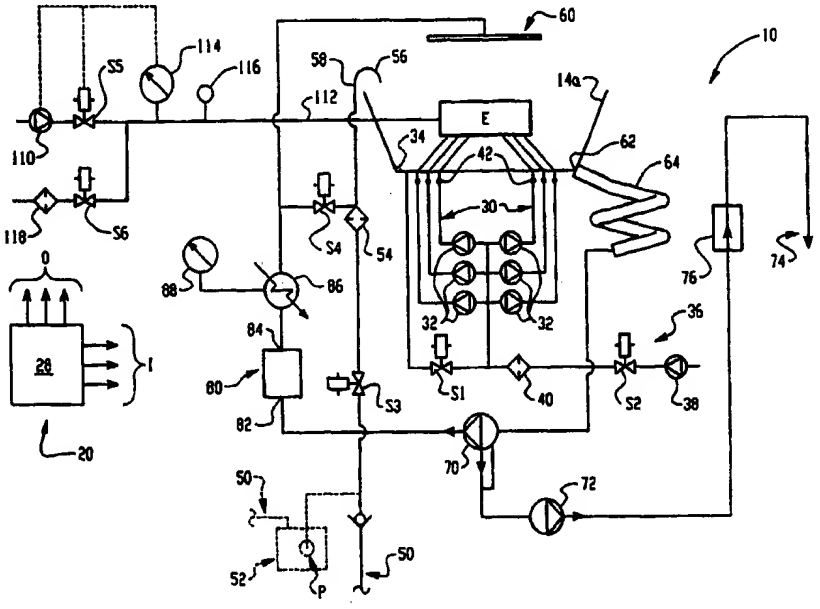
(57) Abstract

A decontamination apparatus for medical devices includes a decontamination basin (14a, 14b) with a selectively opened and closed cover member (16a, 16b) to provide selective access to the basin (14a, 14b). A mixing chamber assembly (80) selectively dispenses detergent concentrate and decontaminant concentrate into a liquid to form a liquid cleaning solution or a liquid decontaminant solution, respectively. A source of decontaminated rinse liquid, such as a microbe removal filter (54), is in selective fluid communication with the basin (14a, 14b). A source of anti–microbial liquid is in selective fluid communication with the microbe removal filter (54) and rinse liquid flow paths (58) between the microbe removal filter and the basin for decontaminating the filter (54) and the rinse lines (58). Each channel of a medical device (E) being decontaminated is connected to a channel flush line (30) and a channel pump (32) for flushing the channels of the device (E). A pressure sensor (42) is in communication with each flush line (30) to sense a blockage in the channels of the medical device (E). The channel pumps (32) pump liquid or decontaminated air through the device channels. A leak test system is also provided for testing the integrity of an outer sheath of a medical device (E) such as an endoscope.



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APPARATUS AND METHOD FOR STERILIZING MEDICAL DEVICES

Background of the Invention

The present invention relates to the decontamination arts including the sterilization arts. It finds particular application in conjunction with the decontamination of medical devices, especially medical devices such as endoscopes and other devices having channels or lumens that must be decontaminated after use.

Sterilization is typically defined as the absence of all life forms including bacterial endospores which are the living organisms most resistant to known sterilants. Disinfection, by distinction, only connotes the absence of pathogenic life forms. Herein, the general term, decontamination, will be used to describe both disinfection and sterilization.

Endoscopes and similar medical devices having channels or lumens formed therethrough are being used on an ever increasing basis in the performance of medical procedures. The popularity of these devices has led to calls for improvements in the decontamination of these devices between use, both in terms of the speed of the decontamination and the effectiveness of the decontamination. One drawback associated with many known endoscope decontamination devices is their reliance on reusable glutaraldehyde or the like as a liquid decontaminant solution. While glutaraldehyde is generally effective for disinfection, sterilization with glutaraldehyde can take 10 to 12 hours which is too long in today's healthcare facilities. Another drawback to glutaraldehyde systems is that they sterilize without cleaning, i.e., they leave sterile biological waste matter on the medical instruments.

Another drawback associated with many known decontamination devices is their lack of a decontaminated rinse liquid. Many known decontamination devices are concerned only with cleaning and disinfecting the devices and consequently rely on unfiltered "tap" water for rinsing. Even those that filter or otherwise decontaminate the rinse liquid often do not decontaminate the rinse liquid flow paths between the source of rinse liquid and the decontamination basin under the incorrect assumption that these apparently closed rinse liquid flow paths cannot become contaminated. Thus, with these devices, it is possible for microorganisms to be reintroduced onto the medical device from the rinse liquid. One known endoscope sterilizer does provide a sterile rinse and rinse liquid flow path (STERIS SYSTEM 1®, STERIS Corporation, Mentor, Ohio). However, it would be desirable to include additional features in conjunction with the sterile rinse and sterile rinse flow paths of this unit.

Prior medical instrument decontamination devices do not include a simple and effective means for accurately delivering a select charge of both detergent concentrate and decontaminant concentrate as needed to form a cleaning solution and a decontamination solution, respectively. Instead, many prior devices rely upon a large tank to hold a reusable decontaminant such as glutaraldehyde and rely upon tank of detergent that must be refilled. The need to refill these tanks periodically decreases efficiency and also puts an operator in contact with decontaminant and detergent liquid and vapors. Further, glutaraldehyde is an environmentally hazardous material that needs to be chemically deactivated. Disposal or reprocessing of diluted or contaminated glutaraldehyde is inconvenient and costly.

Furthermore, with these systems, it is possible

for the detergent tank or the decontaminant tank to run dry without the knowledge of the machine operator. Also, it is not always possible to verify that the detergent or decontaminant has actually been properly and accurately dispensed into the decontamination basin. It would be desirable to provide a decontamination apparatus that simply and accurately dispenses a select dose of detergent concentrate and decontaminant concentrate as needed, without requiring tanks to be refilled and without exposing an operator to detergents and decontaminants. It would also be desirable to provide such a system which reduces the possibility that an incorrect amount of detergent or decontaminant will be dispensed.

The present application is therefore directed to a method and apparatus which overcomes these problems and others while providing better overall decontamination results and efficiency.

Summary of the Invention

In accordance with one aspect of the present invention, an apparatus for cleaning and microbially decontaminating a medical device having at least one internal channel formed therein includes a decontamination area for receiving a non-sterile device and at least one pump having an inlet in fluid communication with the decontamination area and an outlet for connection with the at least one internal channel of the device such that liquid from the decontamination area is circulated through the at least one internal channel by the at least one pump. At least one spray nozzle is positioned in the decontamination area and is fluidically connected to the at least one pump to spray liquid onto exterior surfaces of the device in the decontamination area. A source of sterile rinse liquid includes a

microbe removal filter and rinse liquid pathways in selective fluid communication with the pump so that liquid microbial decontaminant is selectively communicated from the decontamination area into the microbe removal filter and through the rinse liquid pathways to microbially decontaminate the filter and the pathways. The apparatus further includes a mixing chamber for sequentially dispensing (i) a detergent concentrate and, thereafter (ii) a microbial decontamination concentrate into liquid passing through the mixing chamber. The mixing chamber is adapted to receive a multi-compartment ampule including a first interior compartment holding a charge of detergent concentrate and at least a second interior compartment holding a charge of microbial decontamination concentrate. A means is provided for sequentially opening the first interior compartment of the ampule to release the charge of detergent concentrate and, thereafter, the at least one second interior compartment of the ampule to release the charge of decontaminant concentrate. An electronic control means is operatively connected to and controls the ampule opening means to open the first interior compartment during a cleaning cycle of the apparatus and to open the second interior compartment during a microbial decontamination cycle of the apparatus.

In accordance with another aspect of the invention, a method of cleaning and sterilizing the exterior surfaces and interior channels of a medical device includes placing the device in a receiving area, circulating a cleaning solution over the exterior surfaces and through the internal channels of the device, and draining cleaning solution from the device receiving area. A rinse liquid is circulated over the exterior surfaces and through the internal channels of the device

in the receiving area and is drained from the device receiving area. Internal channels of the device are flushed with air to remove residual liquid from the channels in the device. The method further includes circulating liquid sterilant over the exterior surfaces and through the internal channels of the device in the device receiving area, circulating the liquid sterilant into a rinse water microbe removal filter and through rinse liquid pathways between the microbe removal filter and the device receiving area to sterilize the filter and pathways, and draining the liquid sterilant from the device receiving area. A rinse water is passed through the microbe removal filter to sterilize the rinse water and the sterile rinse water is communicated through only the previously sterilized rinse liquid pathways to the device receiving area. The sterile rinse water is circulated over the exterior surfaces and through the internal channels of the device in the receiving area, and drained from the device receiving area. The cleaning solution is formed by mixing detergent concentrate with water by opening a first compartment of a multi-compartment container that contains detergent concentrate to dispense the detergent concentrate in the water. The liquid sterilant is formed by mixing sterilant concentrate with water by opening at least a second compartment of the multi-compartment container that contains sterilant concentrate to dispense the sterilant concentrate into the water.

One advantage of the present invention is that it provides an improved decontamination apparatus and method.

Another advantage of the present invention is that it provides for accurately and conveniently dispensing detergent and decontaminant concentrate ingredients into a liquid to form a cleaning solution or

a decontamination solution.

Still another advantage of the present invention resides in the use of a single-use decontaminant.

A further advantage of the present invention is that it provides a decontaminated rinse liquid and decontaminated rinse liquid flow paths for communicating the decontaminated rinse liquid onto and through the channels of the decontaminated medical device.

A further advantage of the present invention resides in its provision of a leak test system for testing the integrity of a sheath or housing forming a part of an endoscope or other device being decontaminated.

A further advantage of the present invention is that it allows each interior flow channel of a medical device to be individually flushed with liquid or decontaminated air and that each interior channel of the medical device can be monitored for blockage.

Yet another advantage of the present invention is the provision of a "break tank" water supply system for isolating the apparatus from a utility or "tap" water supply system.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon their reading and understanding of the following specification of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components and in various steps and arrangements of steps. The drawings are for purposes of illustrating preferred embodiments only, and are not to be construed as limiting the invention.

FIGURE 1 is a front elevational view of a

decontamination apparatus in accordance with the present invention;

FIGURE 2 is a diagrammatic illustration of the decontamination apparatus shown in FIGURE 1, with only a single decontamination basin shown for clarity; and,

FIGURE 3 is an exploded view of a detergent and decontaminant concentrate delivery system in accordance with the present invention.

Detailed Description of the Preferred Embodiment

FIGURE 1 shows a decontamination apparatus for decontaminating endoscopes and other medical devices which include channels or lumens formed therethrough. The decontamination apparatus generally includes a first station **10** and a second station **12** which are at least substantially similar in all respects to provide for the decontamination of two different medical devices simultaneously or in series. First and second decontamination basins **14a,14b** receive the contaminated devices. Each basin **14a,14b** is selectively sealed by a lid **16a,16b**, respectively, preferably in a microbe-blocking relationship to prevent the entrance of environmental microbes into the basins **14a,14b** during decontamination operations. The lids can include a microbe removal or HEPA air filter formed therein for venting.

A control system **20** includes one or more microcontrollers, such as a programmable logic controller (PLC), for controlling decontamination and user interface operations. Although one control system is shown herein as controlling both decontamination stations **10,12**, those skilled in the art will recognize that each station **10,12** can include a dedicated control system. A visual display **22** displays decontamination parameters and machine conditions for an operator and at least one printer **24**

prints a hard copy output of the decontamination parameters for a record to be filed or attached to the decontaminated device or its storage packaging. The visual display **22** is preferably combined with a touch screen input device. Alternatively, a keypad or the like is provided for input of decontamination process parameters and for machine control. Other visual gauges **26** such as pressure meters and the like provide digital or analog output of decontamination or medical device leak testing data.

FIGURE 2 diagrammatically illustrates one station **10** of the decontamination apparatus. Those skilled in the art will recognize that the decontamination station **12** is preferably similar in all respects to the station **10** illustrated in FIGURE 2. However, the station **12** has not been shown in FIGURE 2 for clarity. Further, the decontamination apparatus can be provided with a single decontamination station or multiple stations.

The decontamination basin **14a** receives an endoscope **E** or other medical device therein for decontamination. Any internal channels of the medical device **E** are connected with flush lines **30**. Each flush line **30** is connected to an outlet of a pump **32**. The pumps **32** are preferably peristaltic pumps or the like that pump fluid, such as liquid and air, through the flush lines **30** and any internal channels of the medical device **E**. Specifically, the pumps **32** can either draw liquid from the basin **14a** through a drain **34** and a first valve **S1**, or can draw decontaminated air from an air supply system **36** through a valve **S2**. The air supply system **36** includes a pump **38** and a microbe removal air filter **40** that filters microbes from an incoming air stream. It is preferable that each flush line **30** be provided with a dedicated pump **32** to ensure adequate

fluid pressure and to facilitate the individual monitoring of the fluid pressure in each flush line **30**. A pressure switch or sensor **42** is in fluid communication with each flush line **30** for sensing excessive pressure in the flush line. Any excessive pressure sensed is indicative of a partial or complete blockage, e.g., by bodily tissue or dried bodily fluids, in a device channel to which the relevant flush line **30** is connected. The isolation of each flush line **30** relative to the others allows the particular blocked channel to be easily identified and isolated, depending upon which sensor **42** senses excessive pressure.

The basin **14a** is in fluid communication with a water source **50** such as a utility or "tap" water connection. A pump is optionally provided to boost the pressure of the water from the utility water connection **50**. Alternatively, a "break tank" **52** and an associated pump P provide a source a water which is isolated from the utility connection **50** as is required in certain applications. A valve **S3** selectively blocks the flow of utility water into the basin **14a** from the source **50**. A microbe removal filter **54**, such as a 0.2μm or smaller absolute pore size filter, decontaminates the incoming water which is delivered into the basin through a faucet fixture **56** or the like. A valve **S4** selectively allows the decontaminated water to flow through a rotating spray nozzle assembly **60** to spray decontaminated rinse water into the basin **14a** and onto the medical device **E**. The condition of the filter **54** can be monitored by directly monitoring the flow rate of water therethrough or indirectly by monitoring the basin fill time using a float switch or the like. When the flow rate drops below a select threshold, this indicates a partially clogged filter element that requires replacement.

A basin drain **62** drains liquid from the basin

14a. The drain 62 can include an enlarged helical tube 64 into which elongated portions of the medical device E can be inserted if needed to ensure that the device can be accommodated in the basin 14a. The drain 62 is in fluid communication with a recirculation pump 70 and a drain pump 72. The recirculation pump 70 recirculates liquid from the basin drain 62 to the spray nozzle assembly 60 or otherwise back to the basin to contact the medical device E. The drain pump 72 pumps liquid from the basin drain 62 to a utility drain 74. A flow switch 76 monitors the flow of liquid from the pump 72 to the utility drain 74. The pumps 70,72 can be simultaneously operated such that liquid is sprayed into the basin 14a while it is being drained to encourage the flow of residue out of the basin and off of the device. Likewise, the valves S3 and S4 can be opened while the pump 72 operates to spray decontaminated rinse water into the basin 14a and onto the medical device E during draining operations to provide a better draining of decontaminant or cleaning fluid residue. Of course, a single pump and a valve assembly could replace the dual pumps 70,72.

A mixing chamber assembly 80 includes an inlet 82 in fluid communication with an outlet of the recirculation pump 70. An outlet 84 of the mixing chamber assembly 80 communicates with the spray nozzle assembly 60 through a heating element 86 which selectively heats liquid passing therethrough. A pressure switch or sensor 88 monitors the fluid pressure between the mixing chamber assembly 80 and the spray nozzle assembly 60.

With reference now also to FIGURE 3, the mixing chamber assembly 80 includes an ampule receiving chamber 90 that receives an ampule A or an equivalent container. The chamber 90 is preferably positioned for easy operator

access in the top surface of the basin **14a** and a means is provided for securing an ampule **A** in the chamber **90**. For example, if the chamber **90** is formed in the top surface of the basin **14a**, an inner surface of the lid **16a** can be utilized to secure an ampule in the chamber **90** when the lid **16a** is closed.

The ampule **A** includes a first interior compartment **A1** which contains a detergent concentrate in liquid or dry form. The ampule **A** also includes second and third interior compartments **A2,A3** which contain liquid or dry decontaminant concentrate ingredients. The ampule **A** is made from a frangible material such as plastic and includes a vented foil, paper, or plastic lid to seal its contents while permitting outgassing. Analogously, releasable panels or other closures can separate and provide selective access to the compartments.

As is indicated by the arrow **92**, the ampule **A** is inserted into the chamber **90**. A lance **94** or the like protrudes into the chamber **90** and opens, e.g., pierces, a wall of the first ampule compartment **A1** when the ampule is inserted into the chamber **90**. In this manner, any water or other liquid flowing through the chamber **90** (indicated by the arrows **W**) mixes with the detergent concentrate in the compartment **A1** to form a liquid cleaning solution. The cleaning solution is optionally heated by the element **86** and is communicated into the decontamination basin **14a** through the spray nozzle assembly **60**. The liquid cleaning solution is recirculated with the pump **70** through the spray nozzle assembly **60** to clean the exterior of the device **E** and is recirculated with the pumps **32** to clean any internal channels of the device **E**. After cleaning, the pump **72** removes the detergent and water mixture. Sterile rinse water sterilized by the filter **54** flushes the detergent

and any contaminants resulting from washing operations out of the system. At this point, the pumps **32** are optionally activated along with the opening of the valve **S2** and the operation of the air pump **38** to flush sterile air through all channels of the medical device **E**. This "air rinse" is useful for removing residual sterile water from the channels of the medical device which could undesirably dilute any sterilant subsequently passed through the channels.

In a like manner, the mixing chamber assembly **80** subsequently accesses the second and third interior compartments **A2,A3** to introduce decontaminant concentrate ingredients into water, received through the filter **54**, in the chamber **90** where the ingredients mix with each other and the water to form liquid decontaminant. A preferred decontamination concentrate is a peracetic acid sterilant concentrate described in U.S. Patent 5,077,008, which is expressly incorporated by reference herein. However, any other suitable decontaminant concentrate can be utilized. The mixing chamber assembly **80** selectively accesses the compartments **A2,A3** by advancing the lance **94** further into the chamber **90** (as shown in phantom) to pierce a wall of the compartments **A2,A3**. An actuator **96**, such as one or more solenoids, fluid cylinders, or the like, selectively advances and retracts the lance **94** as indicated by the arrow **98** and optionally rotates the lance **94** as indicated by the arrow **100** to pierce or otherwise access the compartments **A2,A3**. The decontaminant concentrate in the compartments **A2,A3** mixes with clear rinse water or other liquid in the chamber **90** to form a decontaminant solution such as liquid peracetic acid. A seal **S** prevents liquid flow between the outer surface of the lance and the chamber **90**.

Each time decontaminant concentrate is mixed with water or other liquid in the chamber **90** to form the

liquid decontaminant, the valve **S4** is preferably opened (while the valve **S3** remains closed), at least for a select duration, so that liquid decontaminant flows into the microbe removal water filter **54** and the conduit **58** decontaminating the rinse liquid flow paths in their entirety from the filter **54** to the basin **14a**. The liquid decontaminant decontaminates the filter **54** and the flow path **58** to ensure that a truly decontaminated rinse liquid is communicated into the basin **14a** and onto the device **E**.

After the decontamination cycle, the pump **72** drains the decontaminant solution and a sterile rinse is again introduced through the filter **54**. Once any decontaminant residue is flushed from the device **E**, the air pump **38** and the pumps **32** are again activated to pump sterile air, sterilized by the filter **40**, through channels in the device **E** to blow out any trapped liquid. Optionally, the sterile air can be used for partially or for fully drying the device.

Endoscopes and other reusable medical devices often include a flexible outer housing or sheath surrounding the individual tubular members and the like that form the interior channels and other parts of the device. This housing defines a closed interior space which is isolated from patient tissues and fluids during medical procedures. It is important that the sheath be maintained intact, without cuts or other holes that would allow contamination of the interior space beneath the sheath. Therefore, the decontamination apparatus includes means for testing the integrity of such as sheath.

An air pump, either the pump **38** or another pump **110**, pressurizes the interior space defined by the sheath of the device through a conduit **112** and a valve **85**. Optionally, a HEPA or other microbe removing filter

removes microbes from the pressurizing air. An overpressure switch **114** prevents accidental overpressurization of the sheath. Upon full pressurization, the valve **S5** is closed and a pressure sensor **116** looks for a drop in pressure in the conduit **112** which would indicate the escape of air through the sheath. A valve **S6** selectively vents the conduit **112** and the sheath through an optional filter **118** when the testing procedure is complete.

In addition to the input and output devices described above, all of the electrical and electromechanical devices described are operatively connected to and controlled by the control system **20**. Specifically, the switches and sensors **42,76,88,114,116** provide input I to the microcontroller **28** such as a PLC. The PLC **28** receives the input I and controls the decontamination and other machine operations in accordance therewith. For example, the PLC **28** includes outputs O that are operatively connected to the pumps **32,38,54,70,72,110**, the valves **S1-S6**, the mixing chamber assembly actuator **94**, and the heating element **86** to control these devices for effective decontamination and other operations.

Having thus described the preferred embodiments, the invention is now claimed to be:

1. An apparatus for cleaning and microbially decontaminating a medical device having at least one internal channel, said apparatus including a decontamination area (14a) for receiving a non-sterile device (E), at least one pump (32,70) having an inlet in fluid communication with the decontamination area (14a) and an outlet for connection with the at least one internal channel of the device (E) such that liquid from the decontamination area (14a) is circulated through the at least one internal channel by the at least one pump (32,70), at least one spray nozzle (60) positioned in the decontamination area (14a) and fluidically connected to the at least one pump (32,70) to spray liquid onto exterior surfaces of the device (E) in the decontamination area, and a source of sterile rinse liquid including a microbe removal filter (54) and rinse liquid pathways (56), said microbe removal filter (54) and said rinse liquid pathways (56) in selective fluid communication with the at least one pump (32,70) for communicating liquid microbial decontaminant from the decontamination area into the microbe removal filter (54) and through the rinse liquid pathways (56) to microbially decontaminate the filter and the pathways, said apparatus further comprising:

a mixing chamber (80) fluidically connected with the pump for receiving a multi-compartment ampule (A) including a first interior compartment (A1) holding a charge of detergent concentrate and at least a second interior compartment (A2) holding a charge of microbial decontamination concentrate;

an ampule opening means (94,96) for sequentially opening (i) the first interior compartment (A1) of the ampule (A) to release the charge of detergent concentrate and, thereafter, (ii) the at least one second interior compartment (A2) of the ampule (A) to release the charge of decontaminant concentrate such that (i) a detergent concentrate and, thereafter (ii) a microbial decontamination concentrate are sequentially dispensed into liquid pumped through the mixing chamber; and,

electronic control means (28) operatively connected to and controlling the ampule opening means to open the first interior compartment (A1) during a cleaning cycle of the apparatus and to open the at least one second interior compartment (A2) during a microbial decontamination cycle of the apparatus.

2. The cleaning and decontamination apparatus as set forth in claim 1 further comprising:

a source of sterile air (110) in selective fluid communication with the inlet of the at least one pump (32,70) for circulating sterile air through the internal channels of the device (E).

3. The cleaning and decontamination apparatus as set forth in either of claims 1 or 2 wherein said at least one pump comprises:

a plurality of channel pumps (32) each having an inlet in fluid communication with the decontamination area (14a) and an outlet adapted for fluid communication with an internal channel of the device (E); and,

a recirculation pump (70) having an inlet in fluid communication with the decontamination area (14a) and an outlet in fluid communication with the spray nozzle (60).

4. The cleaning and decontamination apparatus as set forth in claim 3 further comprising:

a plurality of fluid pressure sensors (42) respectively in fluid communication with the plurality of channel pump outlets for individually and independently sensing fluid pressure at each channel pump outlet.

5. The cleaning and decontamination apparatus as set forth in any of claims 1-4 wherein said ampule compartment opening means further comprises:

a plunger (94) movable between a first position for opening the first ampule compartment (A1) to dispense the charge of detergent concentrate into a liquid flowing in the mixing chamber (80) and a second position for opening the at least one second ampule compartment (A2) to dispense the charge of decontaminant concentrate into a liquid flowing in the mixing chamber(80); and,

an actuator (96) controlled by the electronic control means (28) for selectively moving the plunger (96) between the first and second positions.

6. The cleaning and decontamination apparatus as set forth in any of claims 1-5 comprising:

a source of pressurized fluid (110) in selective communication with a sealed interior area of the device in the decontamination area; and,

a fluid pressure monitor (116) connected to the sealed interior area for monitoring pressure of the fluid in the sealed interior area.

7. The cleaning and decontamination apparatus as set forth in any of claims 1-6 wherein said electronic control means monitors a flow rate of water through the microbe removal filter (54) to monitor the condition of the filter.

8. A method of cleaning and microbially decontaminating the exterior surfaces and interior channels of a medical device (E) including placing the device in a receiving area, circulating a cleaning solution over the exterior surfaces and through the internal channels of the device, circulating an antimicrobial liquid over the exterior surfaces and through the internal channels of the device, circulating the antimicrobial liquid into a rinse water microbe removal filter and through rinse liquid pathways between the microbe removal filter and the device receiving area to kill microbes in the filter and the pathways, passing rinse water through the microbe removal filter to remove microbes from the rinse water and communicating the microbe-free rinse water through only the previously antimicrobial liquid treated rinse liquid pathways to the device receiving area, and circulating the microbe-free rinse water over the exterior surfaces and through the internal channels of the device, the method characterized by:

opening a first compartment (A1) of a multi-compartment container (A) that contains detergent concentrate to dispense the detergent concentrate;

mixing the dispensed detergent concentrate with water to form the cleaning solution and circulating the cleaning solution over the exterior surfaces and through the interior channels of the device (E);

draining the cleaning solution;

opening at least a second compartment (A2) of the multi-compartment container (A) that contains an antimicrobial concentrate to dispense the antimicrobial concentrate;

mixing the antimicrobial concentrate with water to form antimicrobial liquid and circulating the antimicrobial liquid over the exterior surfaces and

through the interior channels of the device (E);

draining the antimicrobial liquid; and,

rinsing the device (E).

9. The method of cleaning and microbially decontaminating the exterior surfaces and interior channels of a medical device (E) as set forth in claim 8 further comprising:

monitoring a flow rate of water passing through the microbe removal filter (54) to monitor the condition of the filter.

10. The method of cleaning and microbially decontaminating the exterior surfaces and interior channels of a medical device (E) as set forth in either claim 8 or 9 wherein the antimicrobial concentrate mixing step comprises:

opening second and third compartments (A2,A3) of the multi-compartment container (A) together so that antimicrobial concentrate ingredients in the second and third compartments mix together and react in the water to form a peracetic acid.

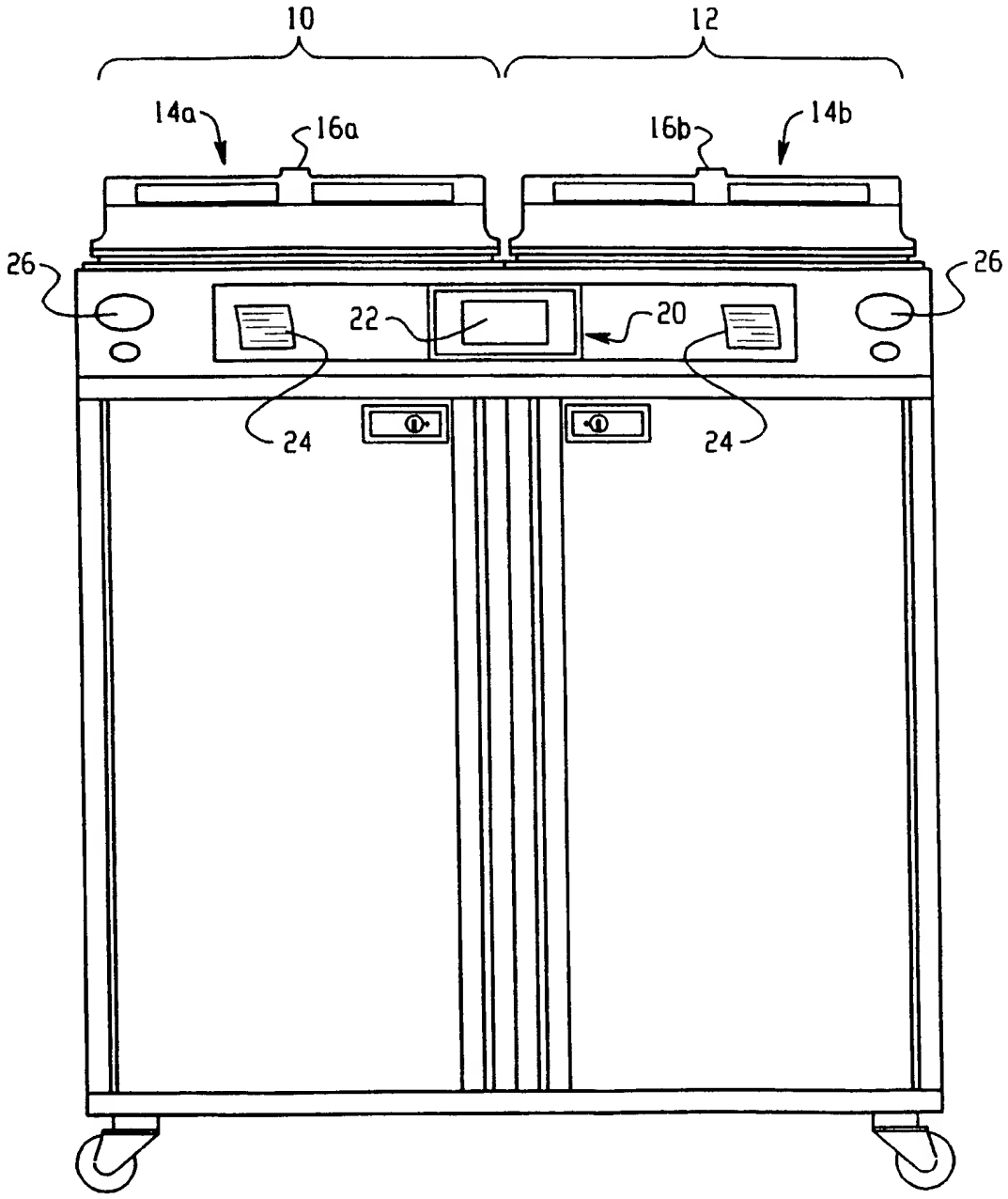

Fig. 1

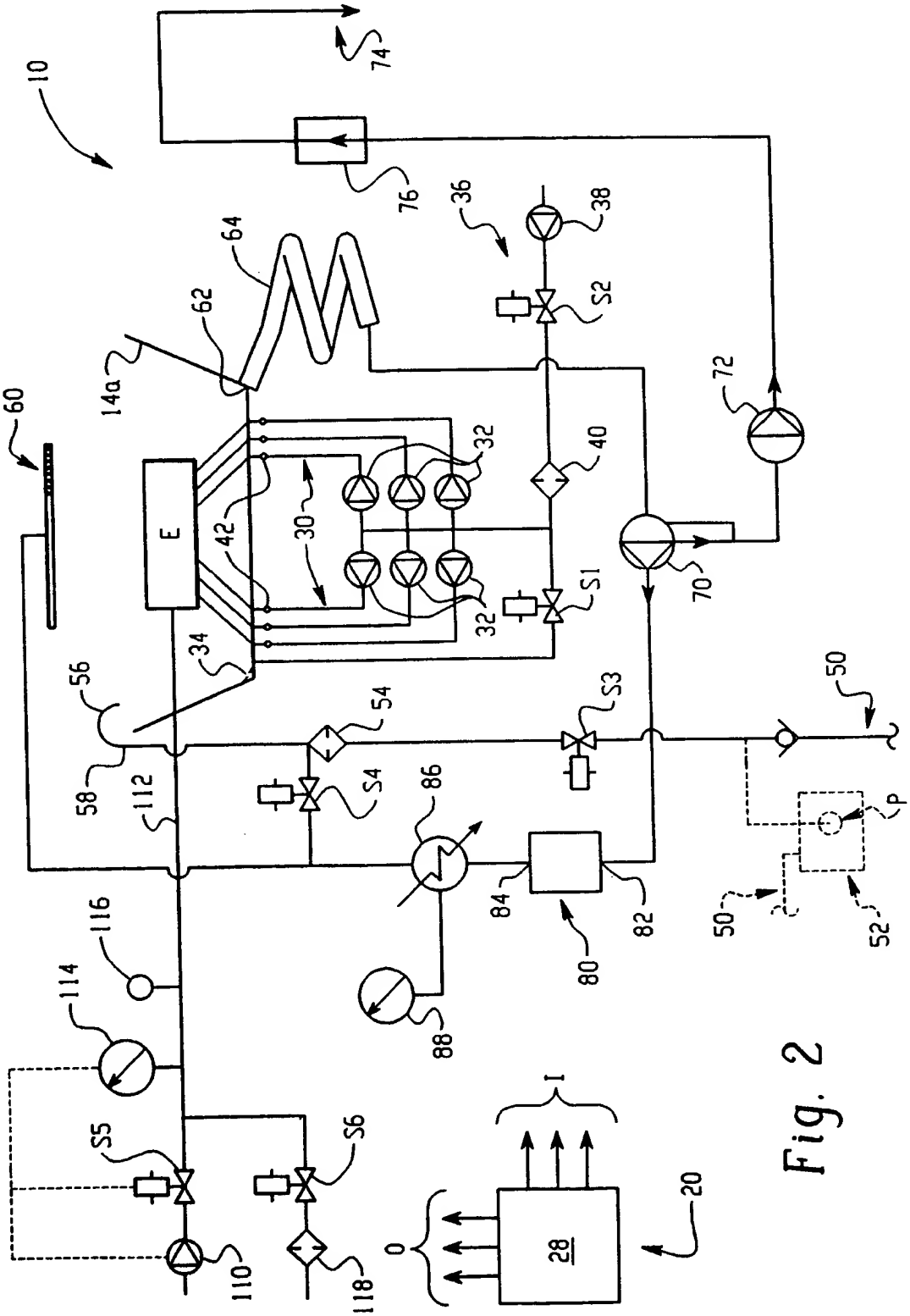
10
74
76
36
38
64
62
S2
14a
72
60
32
40
E
42
30
70
S1
34
56
54
S3
50
58
112
S4
86
P
84
82
50
52
80
116
114
88
S5
S6
110
118
0
1
28
20

Fig. 2

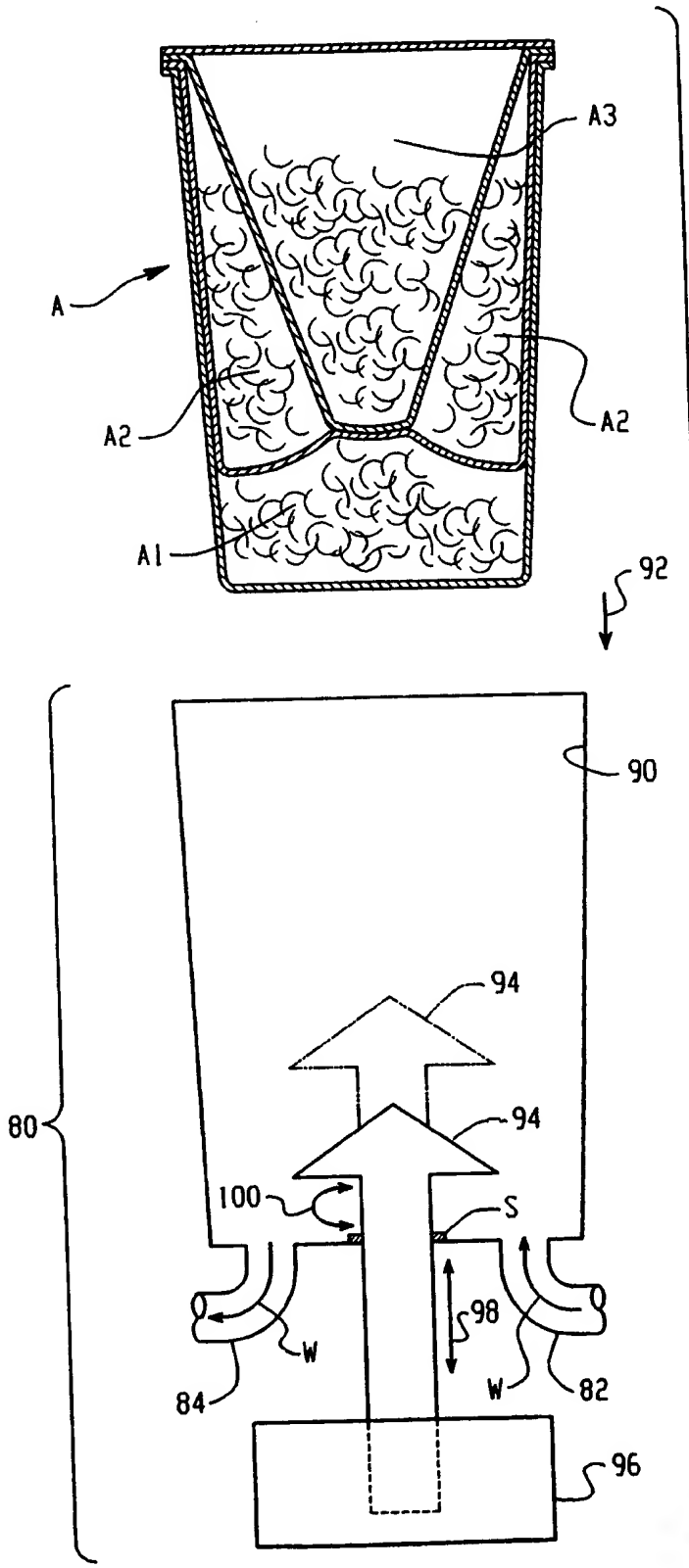

Fig. 3

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(74) Agent: KOCOVSKY, Thomas, E., Jr.; Fay, Sharpe, Beall, Fagan, Minnich & McKee, Suite 700, 1100 Superior Avenue, Cleveland, OH 44114-2518 (US).

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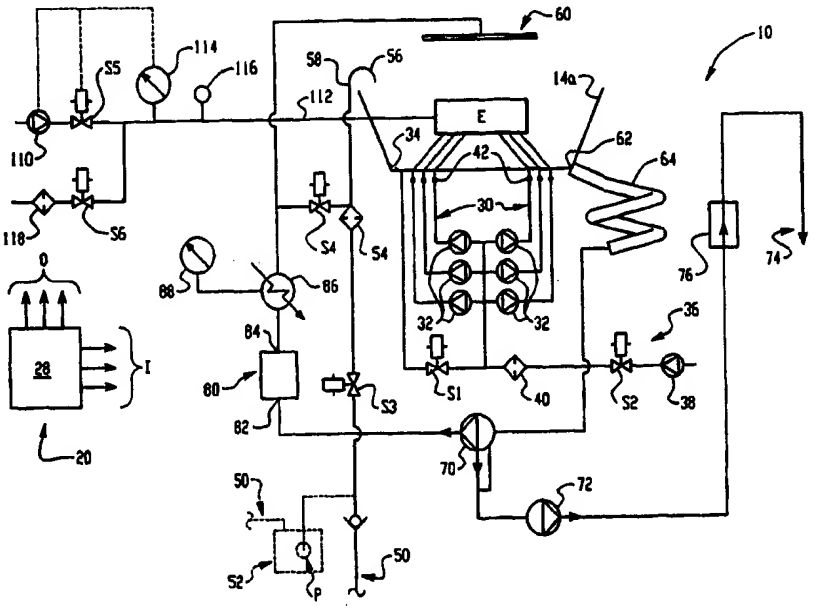
(57) Abstract

A decontamination apparatus for medical devices includes a decontamination basin (14a, 14b) with a selectively opened and closed cover member (16a, 16b) to provide selective access to the basin (14a, 14b). A mixing chamber assembly (80) selectively dispenses detergent concentrate and decontaminant concentrate into a liquid to form a liquid cleaning solution or a liquid decontaminant solution, respectively. A source of decontaminated rinse liquid, such as a microbe removal filter (54), is in selective fluid communication with the basin (14a, 14b). A source of anti-microbial liquid is in selective fluid communication with the microbe removal filter (54) and rinse liquid flow paths (58) between the microbe removal filter and the basin for decontaminating the filter (54) and the rinse lines (58). Each channel of a medical device (E) being decontaminated is connected to a channel flush line (30) and a channel pump (32) for flushing the channels of the device (E). A pressure sensor (42) is in communication with each flush line (30) to sense a blockage in the channels of the medical device (E). The channel pumps (32) pump liquid or decontaminated air through the device channels. A leak test system is also provided for testing the integrity of an outer sheath of a medical device (E) such as an endoscope.



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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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